K112704

DEC 19 2011

510(k) SUMMARY

PREPARATION DATE:	September 12, 2011
APPLICANT:	TearScience, Inc. 5151 McCrimmon Parkway, Suite 250 Morrisville, NC 27560 Tel: (919) 467-4007 Fax: (919) 467-3300
CONTACT PERSON:	Christy Stevens, OD, MPH Vice President, Clinical and Regulatory Affairs
DEVICE TRADE NAME:	LipiFlow® Thermal Pulsation System *Model LFTP-1000, Console and* *Model LFD-1000, Activator (Disposable)*
CLASSIFICATION NAME:	Eyelid Thermal Pulsation System
DEVICE CLASSIFICATION:	Class II; 21 CFR 886.5200
PRODUCT CODE:	ORZ
PREDICATE DEVICE:	LipiFlow® Thermal Pulsation System *Model LFH-1000. Handheld Control System (HCS) and* *Model LFD-1000. Disposable* Class II under 21 CFR 886.5200 Applicant: TearScience, Inc. Cleared under K093937and Evaluation of Automatic Class III Designation on June 28, 2011

DEVICE DESCRIPTION:

The LipiFlow® Thermal Pulsation System is used by a physician in an in-office procedure for patients with chronic cystic conditions of the eyelids to provide controlled heat to the inner eyelid surface, close to the location of the meibomian glands, and intermittent pressure to the outer eyelid to facilitate release of lipid from the cystic meibomian glands. The LipiFlow® System is comprised of physician interface (Control component) and a patient interface (Disposable component). There are two models of the Control component: Model LFH-1000, Handheld Control System (HCS) and Model LFTP-1000, Console. The Console is a change in design from the HCS predicate device model. The LipiFlow® Console was developed from the same treatment control technology as in the LipiFlow® HCS with enhancements in the user interface and power source. Both the Console and HCS work with the same Disposable component (Model LFD-1000), now labeled as Activator (Disposable).

The Activator (Disposable) is a sterile, single-use, biocompatible eyepiece made of polycarbonate and silicone and is inserted around the patient's eyelids. The Activator (Disposable) consists of a combined eye cup and lid warmer with attached tubing and wiring that connect to the Console with a connector.

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The Console is an AC-powered, bench-top device used by the physician to control the application of heat and pressure to the patient's eyelids. The Console consists of a Windows XP embedded computer subsystem with touchscreen display and a software graphical user interface; and treatment hardware for treatment of the patient's right and left eyes using two Activators (Disposables). The Console provides the electrical power, user interface, treatment monitoring, treatment control and safeguard circuitry used for controlling the heat and pressure applied to the patient's eyelids by the Activators (Disposables).

INTENDED USE:

The LipiFlow® Thermal Pulsation System is intended for the application of localized heat and pressure therapy in adult patients with chronic cystic conditions of the eyelids, including meibomian gland dysfunction (MGD), also known as evaporative dry eye or lipid deficiency dry eye.

TECHNOLOGICAL CHARACTERISTICS:

Similarities: The Console and HCS models employ the same principle of operation and work with the same Disposable component, which provides the same Disposable safety features and the same method to prevent re-use of the Disposable. Both models have the same pneumatic and electrical contacts that interface with the Disposable. The Console and HCS both utilize treatment hardware and safeguards to control the application of heat and pressure to the same safe and effective temperature and pressure specifications. Both models use the same 2-minute pressure profiles and same default pressure sequence. The Console provides the user with the same treatment monitoring capability and treatment control features as in the HCS. Both models perform self-tests to ensure proper operation of the Disposable and treatment hardware. Furthermore, the treatment hardware in both models is powered by DC power, and both models comply with the same standards for electrical safety and electromagnetic compatibility (EMC).

Differences: The Console's connector to the Disposable uses a different material than the HCS for more robust use. Compared to the HCS, the Console has minor improvements in the treatment hardware, including temperature and pressure sensing accuracy, redundant pressure sensor tracking, back-up pressure safeguard method, pressure relief, and device self-test features. The Console provides the user with the additional ability to perform independent treatment of both eyes at the same time using two Disposables and to modify the pressure sequence. The Console is a bench-top enclosure; whereas, the HCS is a handheld device that can be placed on a bench-top using an accessory cradle. Compared to the hardware-only interface on the HCS, the Console has a software user interface with a patient database, support for printing and storage of patient records, and an enhanced treatment display format. Furthermore, the user interface and treatment hardware communication is a serial interface in the Console and hardwired in the HCS. The Console uses AC power in place of the battery power in the HCS.

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PERFORMANCE TESTING:

Performance testing was conducted to demonstrate substantial equivalence between the LipiFlow® Console and HCS models and conformance to the *special controls* for an eyelid thermal pulsation system per 21 CFR 886.5200.

1) The Console conforms to the same electrical safety and EMC performance standards as the HCS in support of the change in power source.

2) The Console shows equivalent temperature and pressure performance and safeguard functions as the HCS including in normal operation, during fault conditions and in a direct comparison during treatment of human eyelids. The Console meets the same design requirements as the HCS based on known safe and effective temperature and pressure specifications, previously validated in bench, animal and clinical studies of the LipiFlow® System (refer to K093937).

3) The sterility and shelf-life of the Disposable, which is used with both the Console and HCS models, meets performance standards for sterility and shelf-life testing.

4) The biocompatibility of the Disposable, which is used with both the Console and HCS models, meets performance standards for biocompatibility (refer to K093937).

5) Software verification and validation testing shows the Console software meets design input requirements and user needs. The usability of the Console bench-top design and user interface with touchscreen monitor has been validated to usability standards. Additionally, the Console's software does not control treatment, and a software failure would not affect the hardware's treatment control or the safety circuits.

   Software verification and validation and bench performance testing of the additional user functions show that these functions do not adversely affect safety and effectiveness, and demonstrate substantial equivalence between the Console and HCS models.

   Bench performance testing supports that the minor improvements in the treatment hardware in the Console model do not raise new questions of safety and effectiveness. The Console treatment hardware function was verified and validated to meet design requirements with substantially equivalent performance to the HCS.

CONCLUSIONS:

The LipiFlow® Console and Disposable configuration (Model LFTP-1000 and LFD-1000) has the same intended use and indications for use as the predicate device, the LipiFlow® HCS and Disposable configuration (Model LFH-1000 and LFD-1000). Performance testing demonstrates the Console model is substantially equivalent in technological characteristics to the HCS model. Testing shows that the technological differences between the Console and HCS do not raise new questions of safety and effectiveness, and do not adversely affect safety and effectiveness. Furthermore, performance testing confirms that the LipiFlow® Console and Disposable configuration is at least as safe and effective as the legally marketed LipiFlow® Handheld Control System and Disposable configuration.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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TearScience, Inc.
c/o Christy Stevens, O.D., M.P.H.
Vice President, Clinical and Regulatory Affairs
5151 McCrimmon Parkway, Suite 250
Morrisville, NC 27560

Re: K112704
Trade/Device Name: LipiFlow® Thermal Pulsation System, Models LFTP-1000 and LFD-1000
Regulation Number: 21 CFR 886.5200
Regulation Name: Eyelid Thermal Pulsation System
Regulatory Class: Class II
Product Code: ORZ
Dated: November 15, 2011
Received: November 16, 2011

Dear Dr. Stevens:

This letter corrects our substantially equivalent letter of December 19, 2011.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known): K112704

Device Name: LipiFlow Thermal Pulsation System,
Models LFTP-1000 and LFD-1000

Indications For Use: The LipiFlow Thermal Pulsation System is intended for the application of localized heat and pressure therapy in adult patients with chronic cystic condictions of the eyelids, including meibomian gland dysfunction (MGD), also known as evaporative dry eye or lipid deficiency dry eye.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Marc Robboy

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

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